



June 17, 2024

DePuy Synthes
Nicole Aeschbacher
Senior Regulatory Affairs Specialist
Eimattstrasse 3
Oberdorf, 4436
Switzerland

Re: K233256
Trade/Device Name: Robotic Integration Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 13, 2023
Received: June 10, 2024

Dear Nicole Aeschbacher:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir - Digitally signed by
Jesse Muir -S
Date: 2024.06.17
10:37:14 -04'00'

For: Shumaya Ali, M.P.H.

Assistant Director

DHT6C: Division of Restorative, Repair
and Trauma Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K233256

Device Name

Robotic Integration Instruments

Indications for Use (Describe)

Robotic Integration Instruments are reusable instruments indicated to be used during the preparation and placement of DePuy Synthes screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or percutaneous procedures. The Robotic Integration Instruments are designed for use with only the specific DePuy Synthes implant system(s) for which they are indicated and with the VELYS Robotic-Assisted Solution for Spine. The Robotic Integration Instruments are indicated for use in surgical spinal procedures, in which:

- the use of EXPEDIUM, VIPER, TriALTIS and SYMPHONY OCT is indicated,
- the use of stereotactic surgery may be appropriate, and
- reference to a rigid anatomical structure, such as the pelvis or a vertebra can be identified relative to the acquired image (eg. CT or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.

These procedures include but are not limited to spinal fusion. The Robotic Integration Instruments are also compatible with DePuy Synthes Power Systems and the Medtronic IPC® POWEREASE System.

The Robotic Integration Instruments used in conjunction with the SYMPHONY OCT system are intended to support indicated cervical and thoracic polyaxial screw placement only.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

A. Submitter Information

510(k) Sponsor: Medos International, SARL

Contact Person: Nicole Aeschbacher
Senior Regulatory Affairs Specialist
Eimattstrasse 3
4436 Oberdorf BL
Switzerland

Telephone: +41-61-5641798

Email: naeschba@its.jnj.com

B. Date Prepared 13 Oct 2023

C. Device Name

Trade/Proprietary Name: Robotic Integration Instruments

Common/Usual Name: Orthopedic Stereotaxic Instrument

Device Classification and Regulation: Class II
OLO – 21 CFR §882.4560

Classification Product and Panel Code OLO – Neurology

D. Predicate Device Names

Primary Predicate Device:
Navigation Enabled Instruments (K200791) – OLO

Additional Predicate Device:
E-GPS Navigated Instruments (K220862) – OLO

Reference Device:
TriALTIS Navigation Enabled Instruments (K231527) – OLO

E. Device Description

Robotic Integration Instruments are reusable instruments used for the preparation and placement of DePuy Synthes screws (EXPEDIUM, VIPER, TriALTIS and SYMPHONY OCT), in either open or percutaneous procedures. The Robotic Integration instruments consist of a collection of Array Sleeves, Access Guides, Drills, Taps and Screwdrivers as well as various accessories and are designed for robotic assisted, navigated and non-navigated use. They can be operated manually or under power. Navigation and Robotic Guidance of these instruments is achieved using the VELYS Robotic-Assisted Solution for Spine and associated and compatible VELYS Spine Instrument Arrays. The Core Instrument is a Navigation Ready Instrument, navigation of this instrument is achieved using a Universal Navigation Adaptor Set (UNAS) Navigation Ring and compatible VELYS Spine Instrument Arrays.

F. Indications for Use

Robotic Integration Instruments are reusable instruments indicated to be used during the preparation and placement of DePuy Synthes screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or percutaneous procedures. The Robotic Integration Instruments are designed for use with only the specific DePuy Synthes implant system(s) for which they are indicated and with the VELYS Robotic-Assisted Solution for Spine. The Robotic Integration Instruments are indicated for use in surgical spinal procedures, in which:

- the use of EXPEDIUM, VIPER, TriALTIS and SYMPHONY OCT is indicated,
- the use of stereotactic surgery may be appropriate, and
- reference to a rigid anatomical structure, such as the pelvis or a vertebra can be identified relative to the acquired image (eg. CT or 3D fluoroscopic image reconstruction) and/or an image data-based model of the anatomy.

These procedures include but are not limited to spinal fusion. The Robotic Integration Instruments are also compatible with DePuy Synthes Power Systems and the Medtronic IPC® POWEREASE System.

The Robotic Integration Instruments used in conjunction with the SYMPHONY OCT system are intended to support indicated cervical and thoracic polyaxial screw placement only.

G. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

Based upon the information provided in this premarket notification, it is concluded that the subject devices are as safe and effective and perform as well as the predicates. Substantial equivalence was established in terms of design features, technological characteristics and intended use as compared to the predicate devices.

Compared to the predicate devices, the Robotic Integration Instruments share similar design and dimensions, indications for use, materials, and principles of operations. This does not raise new questions of safety and effectiveness based on application of recognized consensus standards and design controls.

H. Materials

The Robotic Integration Instruments are manufactured from stainless steels, Titanium or PEEK (Polyetheretherketone), from which several of these devices (Core Instrument Levers, Array Guide Levers, Array Sleeve Plungers, Array Sleeve Tubes, Array Sleeve Stop Wheel, Driver Threadlocker Handle) are coated with Tungsten Carbide Carbon and the Cervical CFX Taps with Titanium Nitride.

I. Performance Data

The performance data for the subject devices consists of the following evaluations:

- Accuracy Verification through engineering analysis,
- Fulfillment of navigation systems instrument accuracy requirements as stated by the navigation manufacturer,
- CAD Model Evaluation,
- Simulated Use Evaluation.

J. Conclusion

The indications for use of the Robotic Integration Instruments are consistent with those of the predicate devices. The technological characteristics of the Robotic Integration Instruments in terms of design, materials and performance are consistent with those of the predicate devices. The Robotic Integration Instruments are substantially equivalent to the predicate devices.